

REMARKS

RESPONSE TO ELECTION/REQUIREMENT FOR RESTRICTION

The Applicants are required to restrict their invention to one of the following groups. Groups I and II are directed to a compound or composition of formula III, according to Claims 1-20. Group III is directed to a compound or pharmaceutical composition of a formula as drawn up by the Examiner. Group IV is directed to a compound or pharmaceutical composition of Formula I, according to Claims 1-11 and 18-20, which is not encompassed by Groups I-III; and Group IV may be subject to further restriction by the Examiner. Groups V-VIII are directed to a method of modulating and/or inhibiting a kinase, as in any one of Groups I-IV, according to Claims 21-26. The Applicants are required to elect a single species for examination on the merits.

The Applicants elect, with traverse, Group II directed to “compounds and compositions of Formula III, wherein R13 [is] selected from the list of phenyl, alkyl, H, alkoxyalkyl, aminoalkyl, piperidinealkyl, N-morpholinyl, pyrrolidinyl, R10=H, alkyl, nitro, alkoxy, amino, halo, cyano, -CNH(NH2), trifluoromethyl, R12=H, C2-4 alkyl, R4/R5=H, halo, C1-2alkyl.” The Applicants elect the following species: (3*Z*)-3-[(2-fluorophenyl)(4-methyl-1*H*-imidazol-2-yl)methylidene]-5-[(1-ethylpiperidin-4-yl)amino]-1,3-dihydro-2*H*-indol-2-one, the compound of entry 113 in Table 1 on page 31 of the Specification. Pending, currently-amended Claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 12, 13, 14, 15, 16, 17, 18, 19, and 24 and new Claims 27, 28, 29, 30, and 37 read on the elected species.

The Applicants understand the election to be provisional and that Group II will be examined with respect to the elected species and if found to be patentable, the examination will be extended to the other Markush group members set forth in Groups I, II, III, and IV. Further, the Applicants understand that method claims as described in Groups V-VIII will be rejoined if the product claims from which they depend are found allowable. To the extent that the Examiner intends that the Applicants amend their generic claims to excise non-elected subject matter, the Applicants respectfully traverse this Restriction Requirement. The Applicants request clarification of the status of the nonelected subject matter and whether it is to be permanently withdrawn from

consideration. The Applicants also respectfully request reconsideration of the restriction for the following reasons:

ARGUMENTS

Applicants request reconsideration of the restriction because the restriction groups as drafted by the Examiner do not match the scope as of the claims as drafted by the Applicants. For Groups I and II, the Applicants respectfully point out that the groups the Examiner includes for R¹² and R¹³ do not fall within the scope of Formula III as described by the Applicants in Claim 12. As described by the Applicants in original Claim 12, Formula III is directed to a Compound where R¹² is C₁₋₄alkyl only, not hydrogen and C₂₋₄alkyl as described by the Examiner. In addition, the Applicants described R¹³ in Formula III as being selected from “H, an optionally substituted alkoxy group, an optionally substituted amino group, and an optionally substituted heteroalicyclic,” and not “phenyl, alkyl, H, alkoxyalkyl, aminoalkyl, piperidinealkyl, N-morpholinyl, pyrrolidinyl” as described by the Examiner. Finally, as described by the Applicants, R¹⁰ in Formula III does not include cyano as the Examiner has stated in Groups I and II.

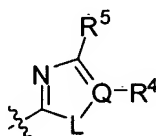
The Applicants understand that the requirement for Unity of Invention is met where the invention forms a single general inventive concept (PCT Rule 13.1) which requirement is fulfilled when there is a

technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression ‘special technical features’ shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art”

(PCT Rule 13.2, emphasis added). More particularly, § 1850 of MPEP addresses unity of invention for chemical compounds in a Markush. For a Markush grouping of alternative chemical compounds, the requirement of a technical interrelationship involving the same or corresponding special technical features are met when the alternatives are of a similar nature. Alternatives are of a similar nature when “(A) [a]ll alternatives have a common property or activity; and (B) (1) [a] common structure is present, i.e., a significant structural element is shared by all of the alternatives...” (*id.*). A shared, significant

structural element is met where the “compounds share a common chemical structure which occupies a large portion of their structures” (*id.*). The Applicants submit that the invention meets the above requirements for unity of invention.

The Examiner states that Groups I-VIII do not relate to a single general inventive concept because “... they lack the same or corresponding special technical features” [Restriction Requirement dated February 4, 2008 (hereinafter “Restriction Requirement”), page 5]. The Examiner describes the special technical feature of this invention as “the common core found in Formula I” (Restriction Requirement, page 6). However, the Examiner earlier describes the special technical feature (Restriction Requirement, page 5) in ways that break up the common core that Formula I, *as a whole*, describes. The common core of the Applicants invention is not a methylene indolinone. The common core is Formula I in its entirety – a methylene indolinone where at least one of R¹ is an -A-R⁷ group (and R⁷ is a heteroalicyclic group) and also where the exo-olefin is substituted with X as well as the group depicted below:



The Applicants respectfully request that the Examiner consider the entirety of the common core of the Invention which is described by Formula I.

The Examiner cites US 6,689,806 (Tang et. al. reference) as evidence that there is no special technical feature which defines a contribution over the art. The Applicants respectfully point out that the compound cited in columns 78-79 does not fall within the scope of Applicants' Formula I. The Tang compound contains a pyrrol-2-yl and the Applicants Formula I encompasses heteroaromatic ring systems that do not include a pyrrol-2-yl and further require that at least one more heteroatom be present in the ring. In addition, the Applicants' Compound of Formula I requires that one R¹ be an -A-R⁷ group where R⁷ is a heteroalicyclic group and the Tang is not similarly substituted. The Applicants respectfully submit that the Examiner has not considered Applicants' invention as a whole and that Formula I, when considered as a whole, does provide a contribution over the art. The requirements for unity of invention, as understood by the Applicants, have been met.

On page five of the Restriction Requirement, the Examiner discusses various ring systems when he described the special technical feature, as viewed by the Examiner, of the Applicants invention (Restriction Requirement, page 5). The Applicants respectfully request clarification of which rings the Examiner is discussing as not being equivalent and also what the basis is for the determination.

The Applicants also note that separate search classifications cannot form the basis of a lack of unity of invention issue. It appears to the Applicants that the Examiner has done exactly this by creating groups based on classifications (Restriction Requirement, page 7). The Applicants respectfully turn the Examiner's attention to § 1850 of the M.P.E.P. which states that lack of unity of invention should not be raised "merely because the inventions claimed are classified in separate classification groups or merely for the purpose of restricting the international search to certain classification groups." This is what the Examiner has appeared to do when he divided the Applicants' composition of matter claims into four different groups.

The proper treatment of the restriction of Markush-type claims is described in § 803.02 of the M.P.E.P. Accordingly, the Examiner may require that the Applicants elect a particular species for examination; however, this is a procedural tool and cannot be used as the basis for requiring amendment of the scope of a generic claim to excise non-elected species. If the elected species is ultimately found patentable, then examination is extended to the provisionally withdrawn subgenera. If a species is examined on the merits and found unpatentable, the examiner then may reject any claims which read on the unpatentable species. This rejection may be overcome by amendment. Thus, the prior art search is not extended unnecessarily and the applicant's invention, as he or she contemplates it, is examined on the merits. Here, it appears that the Examiner will not examine the non-elected groups and that the non-elected subject matter will be withdrawn permanently from the claims. While it is proper to withdraw non-elected subject matter *provisionally* during an examination of a species, it is improper to withdraw *permanently* from consideration all non-elected species. To the extent that the Applicants will be required to withdraw non-elected subject matter permanently from consideration, this will include the withdrawal of entire claims that are sub-genuses of the most generic Markush claim, and/or parts of individual claims. Neither the M.P.E.P. nor the courts

allows this (See *In re Haas*, 486 F.2d 1053 (C.C.P.A. 1973) (*Haas I*) (further proceedings at *In re Haas*, 580 F.2d 461 (C.C.P.A. 1978)). The Applicants respectfully request that the Examiner clarify whether he intends to withdraw nonelected subject matter permanently from consideration.

By dividing the scope of the invention into eight groups, the Examiner, rather than the Applicants, has defined the form in which the invention is claimed which is not permitted by the courts. (See *In re Weber*, 580 F.2d 455 (C.C.P.A. 1978)). An applicant has a right to have each claim examined on the merits in the form she or he considers to best define her or his invention. (*Id.*; see also 35 U.S.C. § 112, second paragraph and *In re Wolfrum*, 486 F.2d 588, 591 (C.C.P.A. 1973).) Here, the Examiner has drafted genres and in doing so defines the invention for the Applicants which is improper.

The Examiner's basis for the Restriction Requirement is that invention as described by the Applicants contains independent or distinct inventions (Restriction Requirement, page 6). The Applicants make no assertion whether their generic claims contain independent and distinct inventions.¹ Nevertheless, the Applicants note that Markush claims are allowed to contain independent and distinct inventions as stated in § 803.02 of the M.P.E.P.:

A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s).

(See also 37 C.F.R. § 1.141 (a) which states that entire claims that are dependent on the most generic claim of the invention are allowed to contain independent and distinct inventions provided there is an allowable claim generic to all the claimed species.) Where there is a claim includes all of the limitations of the generic claim from which it depends, it is entirely proper for it to contain species that may be independent and distinct. The Applicants therefore assert that whether or not the invention contains independent and distinct inventions is not at issue under restriction practice.

¹ Contrary to the Examiner's discussion of "independent or distinct species" and of the invention containing "groups of inventions," it should be noted that the Applicants consider the Application to contain one invention of which there are different aspects.

Finally, the Examiner states that “there would be a serious search and examination burden if restriction were not required” (“Restriction Requirement,” page 7). The Applicants respectfully point out that the Examiner is not required to examine every species. (Please see M.P.E.P. 803.02 which requires that only a reasonable number to determine whether the entire genus is allowable.) Even assuming that there is a burden on the Examiner, the Applicants respectfully submit that when there is a conflict between an applicant’s statutory right to claim the subject matter of her or his invention as she or he sees fit and the Patent Office’s power to regulate the workload of its Examiners, the rights of the applicant must prevail. The Applicants are mindful of the Patent Office’s interest in limiting the burden of the examination in each application; however the court in *Weber* stated that “... in drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights are paramount.” *Id.* at 458-459. The Applicants contend that their right to claim generically their invention prevails over any burden, assuming there is one, on the Patent Office.

The Applicants submit that the U.S.P.T.O. does not have the authority to compel an applicant to divide up her or his generically claimed invention. If, in order to comply with the Restriction Requirement, the Applicants are compelled to divide their generically claimed invention into various subgenus claims, the Applicants will not have their claims examined in the form that they believe best to define their invention. Decisions by the Patent and Trademark Office Board of Patent Appeals and its reviewing court clearly hold that a restriction requirement which compels an applicant to divide a generic claim for the purposes of permanently excising non-elected subject matter is improper and that such a procedure amounts to a rejection. To the extent that the Applicants will be required to withdraw non-elected subject matter permanently from consideration, they submit that the Restriction Requirement is improper.

SUMMARY


In view of the foregoing, the Applicants respectfully request reconsideration of the Restriction Requirement. It is believed that a fee in the amount of \$XX is required with the submission of this response and for a two-month extension of time. Should

additional fees be required to process this submission and any papers attached, the Commissioner is hereby authorized to charge the necessary fees to Deposit Account Number 50-1108.

Respectfully submitted,

May 5, 2008
Date

Exelixis, Inc.
210 East Grand Avenue
PO Box 511
South San Francisco, CA 94083-0511
Tel. (650) 837-7553 (direct)
Fax: (650) 837-8234


Janice V. Wade
Attorney for the Applicants
Reg. No. 50,606